USE OF CONTROLLED EXPOSURE TO PIG Faeces AS A DISEASE CONTROL MEASURE
INFORMATION FOR VETERINARY PRACTITIONERS – JUNE 2014

1. BACKGROUND
The issue of the use of what is commonly known as “feedback” of pig manure, digestive tract content (DTC) or bedding contaminated with pig faeces (hereafter referred to as “controlled exposure”) as a disease control measure has become particularly relevant in the light of reports since May 2013 of the emergence of virulent porcine epidemic diarrhoea (PED) in North America. Whilst PED virus is not new to GB, the strains emerging elsewhere in the world are new variants to which the GB national herd may have no immunity. Exposure of pregnant sows to infected material is being promoted as a control measure for PED in North America and, based on past experience from historical outbreaks of both PED and another enteric coronavirus, transmissible gastroenteritis (TGE) in GB, it is very likely that veterinary surgeons attending pigs would wish to use the same principle to assist in the control of the disease if virulent PED emerged in the UK. The principle of exposing pigs to the presumed infected faeces of other pigs for disease control is a long established and well recognised disease control measure for both epizootic and endemic disease where no effective pharmaceutical or biological preparation is available.

Deliberately moving manure or DTC into a group of pigs, or providing pigs with access to a liquid mixture containing manure or DTC, for the sole purpose of exposing the pigs to it for disease control purposes, is not feeding in terms of providing nutrition to the animal. However, they may consume it and feeding of manure or DTC to farmed animals is not permitted under EU Animal By Products and feed legislation. Legal advice to the Defra Animal By Product (ABP) policy team has concluded that the only way that exposing pigs to manure or DTC can be lawful is if it has been authorised under ABP legislation articles 36 and 39 of Reg. EC 1069/2009 under the principle of safe end use (see below). The information in this document has been compiled by members of the Pig Veterinary Society Executive Committee in discussion with colleagues in the Animal Health and Veterinary Laboratories Agency and Defra and is for veterinary surgeons attending pig units. It outlines the legal, ABP, welfare and other issues that need to be considered where controlled exposure is used as a disease control measure and provides guidelines for veterinary surgeons to follow when advising its use.

The guidelines indicate an approach to the use of controlled exposure for disease control that is considered lawful if the recommendations are followed. They include a specific requirement that the procedure must be advised and documented by the attending veterinary surgeon on a farm-by-farm, disease-specific basis. This will include regular review and amendment of agreed procedures.

These agreed guidelines will be reviewed and, if appropriate, amended in the event of changes in the evidence available, disease threats or other concerns.

2. LEGAL POSITION

2.1 ABP regulations do not permit feeding of manure or digestive tract content to farmed animals because the permissible routes for use or disposal of category 2 ABPs, laid down in article 13 of Reg. EC 1069/2009, do not include feeding to farmed animals as an option. Manure and DTC are category 2 ABPs under Reg. (EC) 1069/2009 (article 9(a)). The definition of manure under the same regulation (article 3, point 20) is as follows: “‘manure’ means any excrement and/or urine of farmed animals other than farmed fish, with or without litter”. The definition of DTC under Reg. (EU) 142/2011 (Annex I, point 24) is as follows: “‘digestive tract content’ means the content of the digestive tract of mammals and ratites”.

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2.2 EU feed legislation specifically prohibits the feeding of "faeces, urine and separated digestive tract content resulting from the emptying or removal of digestive tract, irrespective of any form of treatment or admixture". It is the first item on the list of prohibited material published as Annex III to Regulation 767/2009 on the marketing and use of feed; but the prohibition itself was first introduced by Decision 91/516 of 9 October 1991. As controlled exposure using manure or DTC is not intended as a means of feeding, feed legislation does not apply.

2.3 However, there is provision for the use of products derived from Animal By Products, such as manure and DTC, under strict conditions and according to Reg. (EC) 1069/20009 articles 36 and 39 to ensure safe end use.

According to Reg. (EC) 1069/20009 article 36:
Operators may place on the market derived products other than the products referred to in Articles 31, 32, 33 and 35, provided:
(a) those products are:
(i) not intended for use for the feeding to farmed animals or for application to land from which such animals are to be fed; … and
(b) they ensure the control of risks to public and animal health by:
(i) safe sourcing in accordance with Article 37
(ii) safe treatment in accordance with Article 38, where safe sourcing does not ensure sufficient control; or
(iii) verifying that the products are only used for safe end uses in accordance with Article 39 where safe treatment does not ensure sufficient control.

According to Reg. (EC) 1069/20009 article 39:
Safe end uses shall include the use of derived products:
(a) under conditions which pose no unacceptable risks to public and animal health; or
(b) which may pose a risk to public and animal health, for specific purposes provided that such use is justified by objectives set out in Community legislation, in particular for the protection of public and animal health.

The interpretation of the above articles is that pig faeces, bedding contaminated with faecal material or DTC may be used as a “derived product” in certain circumstances as a disease prevention/control measure if they are not intended to be fed to animals in terms of providing nutrition to them, and under the principle of “safe end use”, i.e. provided that:
a) any risks to public and animal health that may arise from this practice are controlled,
b) the practice is documented and appropriately controlled,
c) strict conditions are applied as detailed in sections 3 and 4 below, and
d) pig producers and veterinary surgeons attending pigs recognise that each case needs to be supported by unequivocal veterinary opinion that controlled exposure is necessary to reduce or prevent levels of disease on any particular holding.

2.4 The route of administration of the controlled exposure to the pigs must not be by direct incorporation of pig manure, contaminated bedding or DTC in pig feed or in drinking water. Feed and drinking water are to be kept clean and safe.

2.5 Veterinary surgeons have a duty to control disease and alleviate suffering and have sworn an oath when becoming an RCVS member declaring that "...ABOVE ALL, my constant endeavour will be to ensure the health and welfare of animals committed to my care." The code of professional conduct for veterinary surgeons states that veterinary surgeons must make animal health and welfare their first consideration when attending to animals. It may be argued that for some diseases where lactogenic immunity is important in control (e.g. principally enteric viruses affecting preweaned pigs) and where there is no vaccine available for use, the attending veterinarian is presented with a dilemma - there is an intervention available which, if not used, may mean that they are not doing everything possible to control the disease and prevent suffering.
2.6 For disease control purposes, the feeding to farmed animals of animal tissues, including those which have been processed in approved establishments, is prohibited under a combination of the ABP and Transmissible Spongiform Encephalopathies (TSE) Regulations, with a few low risk exceptions which are not relevant to these guidelines. Intraspecies recycling i.e. the feeding of terrestrial animals of a given species with processed animal proteins of the same species is specifically banned in order to control the spread of TSEs and to prevent new novel TSEs arising. It is not permitted that pig tissues are used as a derived product for disease control. This information and guidance note refers only to the use of pig manure, DTC or bedding contaminated with pig manure. Veterinary surgeons should ensure clients are aware that other control methods being used elsewhere (and freely communicated on websites) may not be supported as recommended control methods in the UK and, in some instances, may not be lawful.

3. SAFE END USE GUIDELINES

3.1 Where there are no or few effective alternative control measures or no effective authorised veterinary medicinal products in the UK for treatment or prevention of a disease, the principle of "safe end use" allows the attending veterinary surgeon to recommend controlled exposure of pigs to pig manure, DTC or bedding contaminated with manure as a disease control measure within that pig farm (or a closely linked farm as detailed in section 3.5), in particular to avoid causing unacceptable suffering and protect pig health and welfare. Possible examples of occasions when this might arise include emergence of virulent PED, re-emergence of TGE or endemic PED, outbreaks of rotaviral enteritis.

3.2 The following should be considered by the veterinarian:
   a) the expected efficacy of use should provide better benefits to animal health than lack of use i.e. morbidity (including severity and duration) and/or mortality should be reduced by using this approach
   b) there should not be a likelihood of unacceptable risks to public and animal health from use
   c) there is a need to record that the veterinarian has considered a and b above.

3.3 Documentary evidence of the veterinary advice given must be kept on farm, including how controlled exposure should be performed and the suspected or confirmed disease(s) for which it is being used. This written advice should be kept on farm. It is recommended that this is included in the Veterinary Health Plan or as a separate instruction sheet, which should be dated, regularly reviewed and updated with any amendments to agreed protocols.

3.4 Documentary evidence should include the following at minimum:
   a) Name and address of farm on which controlled exposure is undertaken
   b) Name and address of farm from which derived products are sourced
   c) Where a and b differ, the reason why the two premises are linked for controlled exposure
   d) Name and address of attending veterinary surgeon
   e) Date veterinary advice first given to use controlled exposure
   f) Disease for which controlled exposure is being used to control
   g) Age group of pigs in which disease being prevented
   h) Age group of pigs from which derived products are to be obtained
   i) Age group/stage of production of pigs to be exposed to derived products
   j) The specific nature of the derived products used for controlled exposure
   k) Practical advice on how controlled exposure should be undertaken (see section 5) to include the method of administration
   l) Dates of reviews and any amendments

3.5 In order to comply with the need for safe end use in article 39 of Reg. (EC) 1069/20009, controlled exposure can only occur on the farm where the disease is present using derived products from pigs within that same farm, with a few very specific exceptions to this where premises are closely linked as in one of the following situations:
   a) when replacement breeding gilts are kept at a site separate to the breeding farm which they will enter later. In this situation, the link can only be between one breeding farm and the gilt unit and is not

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intended to allow controlled exposure from several recipient breeding farms to a single breeding gilt source.
b) when breeding sows or gilts are moved from one site to a different one to farrow, as might arise when an outdoor herd moves sites
c) when pigs are weaned to a rearing unit separate from the breeding unit. In this situation, to permit controlled exposure, the faeces from pigs on the rearing pig can only be moved to the source breeding unit if the rearing site receives pigs only from that breeding unit (single source) and would not be permitted if the rearing site received pigs from any other sources.
d) In all cases due consideration should be given to biosecurity before material is transferred.

3.6 It is recommended that the attending veterinary surgeon should make an assessment of the efficacy and safety of the controlled exposure following its implementation and thereafter review the necessity for, and manner of, its use approximately every quarter, for example at routine quarterly visits. This review should be recorded and dated.

4. ADDITIONAL GUIDANCE

4.1 The most likely scenario where controlled exposure would be used for disease control is for a viral disease for which there is no vaccine available. Examples of two such groups of diseases are:

a) neonatal and preweaning diarrhoea caused by organisms for which there is no vaccine available (e.g. PED, TGE, rotavirus). Here it is gilts and sows in late pregnancy which are exposed to (usually piglet) faeces.

b) congenital tremor type A2 and SMEDI not related to porcine parvovirus infection (e.g. due to tescho, sapelo or enteroviruses) for which there are no vaccines. Here it is usually young replacement gilts exposed to faeces prior to service as part of their acclimatisation programme.

The current absence of TGE in GB pigs as a disease entity is suspected to be due to widespread porcine respiratory coronavirus (PRCV, mostly subclinical) infection providing cross-protection against TGE. A re-emergence of TGE might occur if the epidemiology of PRCV should change.

4.2 Whenever the use of controlled exposure for disease control is considered on a pig unit, the following are strongly advised:

a) confirmation of diagnosis of the suspected disease is sought, and differentials are ruled out, by laboratory testing

b) complementary interventions to control disease e.g. improved cleaning and disinfection, improved pig flow, herd closure are also implemented. These interventions should also be documented, for example within the Veterinary Health Plan.

c) evidence is available to support the likelihood that the practice will be beneficial for the suspected disease

d) other potential risks which controlled exposure might pose in the herd, according to its health status, other pathogens and diseases and other considerations, have been considered by the attending veterinary surgeon. Examples might include past detection of Extended Spectrum Beta Lactamase resistance in enteric organisms on the farm or salmonellosis outbreaks in weaners which might cause disease due to Salmonella infection in replacement gilts exposed to their faeces.

4.3 There are specific situations where the use of controlled exposure for disease control should be avoided as it may exacerbate a disease problem; examples are peri-natal erysipelas and porcine reproductive and respiratory syndrome (PRRS) virus infection. Active control of these diseases is essential prior to use of controlled exposure, for example by implementing vaccination. Whenever pig faeces is used as a product for disease control, pigs should be carefully observed for the occurrence of
unexpected clinical signs and, should these occur, the procedure should be stopped immediately and the veterinary surgeon informed.

4.4 Scientific evidence on the efficacy of the use controlled exposure for disease control is limited. Reputable textbooks on pig medicine recommend the method; it is promoted in non-peer reviewed literature and was widely used when TGE and PED outbreaks were occurring in UK pig herds. Effective control of TGE in neonatal pigs relied very heavily on exposure of pregnant sows to infected piglet faeces (no vaccines licensed in UK) and this method was advocated for its control by eminent pig veterinarians from veterinary investigation, practice and academia (Muirhead and Alexander, ed. J. Carr, 2013, Managing Pig Health; Pritchard 1982 Vet Record 110 465-469).

There is reference to the use of controlled exposure as a disease control measure in at least two Chapters of the latest edition of the Diseases of Swine textbook (Zimmerman JJ (ed); Karriker LA (ed); Ramirez A (ed) et al, 2012, Diseases of swine, 10th ed, Wiley-Blackwell, Ames, Iowa, USA). In relation to PED control, this indicates that exposure of pregnant sows to virus using faeces from infected piglets will stimulate rapid lactogenic immunity and shorten the outbreak on the farm (p517)

5. PRACTICAL ADVICE

The detailed manner in which controlled exposure is implemented on individual pig units will vary depending on the management, logistics, disease being controlled and other factors. This section provides generic practical advice.

a) Fresh faeces should be collected from pigs most likely to be excreting the highest amount of the pathogen to which immunity is required. For the major enteric viral diseases (rotavirus, PED, TGE), this is likely to be the faeces of young piglets in the farrowing area, targeting piglets with diarrhoea. For control of enteroviruses, faeces from 6-10-week-old grower pigs may be more appropriate.

b) Grower faeces can easily be collected from the ground with a gloved hand or shovel. Neonatal piglet faeces can be collected by wiping the pen floor with tissue paper, or collecting soiled farrowing pen bedding. Collection of faeces from multiple pigs/pens and mixing the faeces together or pooling in water is ideal.

c) Where piglets are dying before exhibiting diarrhoea, or on outdoor units where collection of piglet faeces is problematic, it may be necessary to collect DTC from dead piglets and the attending veterinary surgeon should demonstrate how to do this to farm staff. Intestines should be removed and rinsed in cold water to wash off contaminating blood. While holding the intestines over a bucket, multiple punctures should be made in small and large intestinal coils using scissors, avoiding cutting off loops of intestine. The intestines can then be swilled in cold water in the bucket to help rinse out intestinal contents. Intestinal tissue must not be included in the derived product.

d) Dilution to extend the material must avoid adverse effects on the virus. Chlorinated, warm or hot water should be avoided and the preparation should be used immediately.

e) For control of piglet diarrhoea due to suspected enteric viral infection, pregnant gilts and sows should be exposed. The material should be presented to the pregnant pigs after about 85 days gestation and up until gilts/sows are moved into the farrowing area.

f) Gilts or sows already in the farrowing accommodation or gilts or sows less than 75 days pregnant should not be exposed. For this reason the method may not be appropriate for use in groups containing pigs at different stages of gestation

g) For the control of, for example, reproductive disease due to suspected enteroviruses, the target pigs are maiden gilts. Controlled exposure can occur in the period between six and two weeks prior to intended service, and should not occur later than two weeks prior to service.

h) Controlled exposure must not involve mixing derived product with feed in feed troughs or with drinking water. This would not be acceptable as the farmer would be offering contaminated feed and unclean drinking water

i) Should any unexpected disease (e.g. erysipelas) or clinical signs (e.g. abortions) occur in the target animals or their litters, the farmer should stop treatment of further groups immediately and inform the veterinary surgeon
6. WELFARE ASPECTS

In addition to the welfare aspects described under 2.5 above, there are also legal requirements under Welfare of Farmed Animals (England) Regulations 2007 (WOFAR), implementing European directive 98/58/EC which state that “Animals must not be provided with food or liquid that contains any substance that may cause them unnecessary suffering or injury and must be provided with food and liquid in a manner that does not cause them unnecessary suffering or injury.” If the guidance in sections 3, 4 and 5 above is followed, the risk that the use of controlled exposure for disease control might cause greater injury or disease than it is preventing is greatly reduced.

Further WOFAR 2007 (implementing 98/58/EC) states that:
“No other substance, with the exception of those given for therapeutic or prophylactic purposes or for the purpose of zootechnical treatment, may be administered to animals unless it has been demonstrated by scientific studies of animal welfare or established practice that the effect of that substance is not detrimental to the health or welfare of the animals.”

Advice from colleagues with welfare expertise emphasises points 3.3 and 3.4 above; that there needs to be written evidence on farm provided by the veterinary surgeon that use of controlled exposure for disease control has been advised. Without this, pig farmers may fall foul of welfare regulations particularly as there are no controlled scientific studies demonstrating efficacy of this approach. This is particularly important for cross compliance and other agri-scheme claimants who could be at risk of legal action and financial penalties if they use controlled exposure of pig faeces without clear veterinary involvement.

Further, the law for pigs requires that in respect to general cleansing and disinfection: “Housing, pens, equipment and utensils used for pigs must be properly cleaned and disinfected as often as necessary to prevent cross-infection and build-up of disease-carrying organisms.” And that “Faeces, urine and uneaten or spilt food must be removed as often as necessary to minimise smell and to avoid attracting flies or rodents.”

Additionally, “Where any animals (other than poultry) are kept in a building they must be kept on, or have access at all times to, a lying area which either has well-maintained dry bedding or is well drained.” and for those kept outside “have access to a well-drained lying area.” Specifically where bedding is provided for pigs: “it must be clean, dry and not harmful to the pigs.”

This means that, aside from any documented procedure agreed with the private veterinarian for using controlled exposure as a method of disease control at specific times, the day to day conditions to which pigs are exposed should continue to comply with the law described above with respect to bedding and lying areas.

7. MANURE AND DTC USE AND DISPOSAL

The question arises whether, if derived products were used for controlled exposure for disease control, ABP regulations would apply if the product (i.e. manure/DTC, bedding contaminated with manure) was moved off farm for use on a specified linked premises or for disposal on fields of other farms. Authorisation D10 does not require commercial documents for the transportation of manure between farms https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/238804/authorisations-20130515.pdf. This also applies to transportation of bedding contaminated with manure. However, commercial documentation is required for the transportation of DTC between farms. ABP Regulations require labelling of vehicles or containers used for transport and storage and need to be complied with. These regulations are available through the following link http://www.defra.gov.uk/ahvla-en/disease-control/abp/

Good personal hygiene and biosecurity precautions should be observed when collecting, transporting and using the derived products. Biosecurity guidance is available through the link below http://www.bpex.org.uk/2TS/health/Biosecurity_documents.aspx
KEY POINTS

- Controlled exposure as a disease control measure is permissible under ABP legislation only if performed under veterinary advice according to specified criteria and documented.
- Controlled exposure must only occur within a single farm with rare specified exceptions (detailed in section 3.5).
- Only pig faeces, bedding contaminated with pig faeces or digestive tract content can be used, not pig tissues or the products of parturition.
- Written details of the veterinary advice regarding controlled exposure must be kept on farm, the information to be included is detailed in section 3.4.
- There should be reasonable expectation from the literature and veterinary knowledge of pig health that controlled exposure is an appropriate control measure for the stated disease(s).
- The use of controlled exposure must not adversely affect pig welfare.
- Controlled exposure should not be by direct incorporation of the product with pig feed or water supply.
- The need for, and efficacy and method of, controlled exposure must be regularly reviewed; evidence of this review must be documented.
- Veterinary surgeons considering advising controlled exposure are strongly advised to read these guidelines in their entirety and maintain a working knowledge of their content.